K110390

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510(k) SUMMARY

Care back pain relief stimulator, K ( )

Date of Submission:	07/27/2011
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1. Proposed Device:

Trade Name:	Care back pain relief stimulator
	Model: TENS 7000,LT3074
Classification Name:	Stimulator, Nerve, Transcutaneous.
	Over-The-Counter
Regulation Number:	21CRF 882.5890
Product Code:	NUH
Device Class:	II

2. Predicate Device:

Predicate Device:	Low Back Pain Relief System
510(k) Number:	K060222
Manufacturer:	Gemore Technology Co.,Ltd

3. Description of Proposed Device:

Care back pain relief stimulator, which includes models TENS 7000 and LT3074 are non-invasive devices which are tented for over the counter use in temporary relief of pain associated with sore and aching muscles in the lower back due to strain form exercise or normal household and working activities.

The devices contain the following main parts: TENS stimulation unit, Support Belt, electrode, and snap cable.

The electrode is permanently sewn up in the support belt. Each belt is flexible, and is available in range of sizes to ensure good patient contact. A male snap connector is placed within the electrode and is connected via the female snap connector to a short lead wire. The lead wire has a female pin connection at the distal end which accepts the lead wire connection from the stimulator.

The device can be worn on the low back part of user so as to place the electrode on the treatment location of low back.

4. Proposed Device Intended Use Statement:

Care back pain relief stimulator is intended for temporary relief of pain associated with sore and aching muscles in the lower back due to strain form exercise or

normal household and working activities.

5. Technological Characteristics:

Both the stimulator and the Predicate device stimulator have the same intended use and fundamental technology. A side-by-side comparison of the technological characteristics of the care back pain relief and the cited predicate devices is included in the 510(k) submission.

Parameter	**Care back pain relief stimulator Model: TENS7000,LT3074**	**Low Back Pain Relief System, model GM320PP**
Indications for use	Care back pain relief stimulator is intended for temporary relief of pain associated with sore and aching muscles in the lower back due to strain form exercise or normal household and working activities.	The model GM320PP is intended for temporary relief of pain associated with sore and aching muscles in the lower back due to strain from exercise or normal household and work activities.
Power Source	9V Battery for TENS7000	9V Battery
	4.5V Battery for LT3074	
Max Output Voltage (V) ±20%	40.0V@500Ω for TENS 7000	40.0V@500Ω
	45.0V@500Ω for LT3074	
	100.0V@2kΩ for TENS 7000	120.0V@2kΩ
	50.0V@2kΩ for LT3074	
	110.0V@10kΩ for TENS 7000	150.0V@10kΩ
	60.0V@10kΩ for LT3074	
Max Output Current (mA) ±20%	80.0mA @500Ω for TENS 7000	80.0 mA @500Ω
	90.0mA @500Ω for LT3074	
	50.0mA @2kΩ for TENS 7000	60.0 mA @2kΩ
	25.0mA @2Kω for LT3074	
	11.0mA @10kΩfor TENS 7000	15.0 mA @10kΩ
	6.0mA @2kΩ for LT3074	
Pulse Width Range	50-300us for TENS 7000	150-260 us
	50-250us for LT3074	
Frequency	2-150Hz for TENS 7000	2-120Hz
	2-110Hz for LT3074	
Timer Range (minutes)	5 - 60 minutes or Continuous fo TENS7000	15min, 30min, 60min and continuous
	30 minutes for LT3074	
Maximum Average Current (average absolute value), mA *(refer to the remark 1)*	3.6mA,500Ω, for TENS 7000	2.5mA,500Ω
	2.5mA,500Ω, for LT3074	
RMS current *(refer to the remark 1)*	17.0 mA.r.m.s for TENS 7000	20.0 mA.r.m.s
	14.2 mA.r.m.s for LT3074	

Maximum Current Density *(refer to the remark 1)*	0.56mArms/cm^2,500Ω for TENS 7000 0.14mArms/cm^2,500Ω for LT3074	0.56mArms/cm^2,500Ω
Maximum Power Density *(refer to the remark 1)*	4.8mWrms/cm^2,500Ω for TENS 7000 1.0mWrms/cm2,500Ω for LT3074	3.3mWrms/cm^2,500Ω
Compliance with Voluntar Standards?	IEC60601-1, IEC60601-1-2 IEC60601-2-10	IEC60601-1, IEC60601-1-2, IEC60601-2-10
Compliance with 21 CFR 898?	Yes	Yes
Weight (grams.)	150 grams with battery for TENS7000 80 grams with battery for LT3074	140 grams with battery
Dimensions (mm.) H x W x T	101*61*24.5cm for TENS7000 85*72*30cm for LT3074	108*61.5*25
Housing Materials & Construction	Enclosure: ABS,94V-1,80℃,UL Approved	Enclosure: ABS,94V-1,80℃,UL Approved
Materials of electrodes:	Rubber or fabric	Gel

6. Non-Clinical Tests Performed:

Care back pain relief stimulator did not conduct, nor rely upon, clinical tests to determine substantial equivalence. Care back pain relief stimulator has received test reports certifying that the Care back pain relief stimulator was tested and found to be in conformity with voluntary standards includes IEC60601, IEC60601-1-2, IEC60601-2-10, ISO 10993 and ISO14971. The software verification has been carried out according to the FDA Guidance of the content of Premarket submissions for the software contained in Medical Devices. This test reports have provided as part of this premarket notification.

7. Conclusions:

The Care back pain relief Stimulator, which includes models TENS 7000 and LT3074, has the same intended use and technological characteristics as the cited predicate device. Moreover, bench testing, safety report and Risk Analysis Report documentation supplied in this submission demonstrates that the difference in the submitted models could maintain the same safety and effectiveness as that of the cited predicate device. In the other words, those engineering difference do not affect the intended use or alter the fundamental scientific technology of the device. Thus, the care back pain relief stimulator is substantially equivalent to the predicate device.

Remark 1

:

TENS 7000 sample calculations:

Maximum Average Current=I max*pulse rate*pulse width=80mA*150Hz*300us*10^{-6}=3.6mA

$$Ir.m.s = \sqrt{\frac{5}{5} * 150Hz * \frac{300us}{1000000}} * 80mA = 17.0mA.r.m.s$$

$$\text{Maximum Current Density} = \frac{\text{Ir.m.s}}{\text{S}} = \frac{17.0mAr.m.s}{30\text{cm}^2} = 0.56mA.r.m.s/cm^2$$

$$Vr.m.s = \sqrt{\frac{5}{5} * 150Hz * \frac{300us}{1000000}} * 40V = 8.5V.r.m.s$$

$$\text{Maximum Voltage Density} = \frac{\text{Vr.m.s}}{\text{S}} = \frac{8.5Vr.m.s}{30\text{cm}^2} = 0.28V.r.m.s/cm^2$$

$$\text{Maximum Power Density} = \frac{\text{Vr.m.s} * \text{Ir.m.s}}{\text{S}} = \frac{8.5Vr.m.s * 17mAr.m.s}{30\text{cm}^2} = 4.8mW.r.m.s/cm^2$$

LT3074 sample calculations:

Maximum Average Current=I max*pulse rate*pulse width=90mA*100Hz*250us*10^{-6}=2.5mA

$$Ir.m.s = \sqrt{\frac{5}{5} * 100Hz * \frac{250us}{1000000}} * 90mA = 14.2mAr.m.s$$

$$\text{Maximum Current Density} = \frac{\text{Ir.m.s}}{\text{S}} = \frac{14.2mAr.m.s}{100\text{cm}^2} = 0.14mAr.m.s/cm^2$$

$$Vr.m.s = \sqrt{\frac{5}{5} * 100Hz * \frac{250us}{1000000}} * 45V = 7.1Vr.m.s$$

$$\text{Maximum Voltage Density} = \frac{\text{Vr.m.s}}{\text{S}} = \frac{7.1Vr.m.s}{100\text{cm}^2} = 0.07Vr.m.s/cm^2$$

$$\text{Maximum Power Density} = \frac{\text{Vr.m.s} * \text{Ir.m.s}}{\text{S}} = \frac{7.1Vr.m.s * 14.2mAr.m.s}{100\text{cm}^2} = 1.0mWr.m.s/cm^2$$

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
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JUL 29 2011

Re: K110390
Trade/Device Name: ETG 255 Combo Stimulator, TEN 260 Stimulator
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: Class II
Product Codes: GZJ, IPF
Dated: November 30, 2011
Received: February 11, 2011

Dear Mr. Jiang Ping:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kevin Alexander
for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number ( ):

Device Name:

ETG 255 Combo Stimulator, TEN 260 Combo Stimulator

Indications for Use:

ETG 255 Combo Stimulator,

For TENS mode

Symptomatic relief of chronic intractable pain, relief of acute post-surgical and posttraumatic pain.

For EMS mode

1. Relaxation of muscle spasm.
2. Increase of local blood flow circulation
3. Prevention or retardation of disuse atrophy
4. Muscle re-education
5. Maintaining or increasing range of motion.
6. Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis

TEN 260 Stimulator

Symptomatic relief of chronic intractable pain, relief of acute post-surgical and posttraumatic pain.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K110390